

Mail Stop Amendment
Attorney Docket No. 24857
App. SN. 10/014,796

REMARKS

Upon entry of the foregoing amendments, claims 1, 4-11 and 26-55 are pending in the application. Claims 12-25 are canceled and claims 2-3 were canceled by a Preliminary Amendment filed on August 29, 2003. Claims 26-55 are added and claims 1, 6-10 are amended to clarify the subject matter of the invention and thereby place the application in condition for allowance.

Basis for the amendments may be found in the specification on page 2, paragraphs 008 and 010. The above amendments do not introduce any new matter within the meaning of 35 U.S.C. §132. Accordingly, entry of the above amendments is respectfully requested.

Regarding the certified priority document and copies of Information Disclosure Statement references, Applicants respectfully note that said copies were re-submitted to the U.S. Patent and Trademark Office on March 25, 2004. Applicants respectfully request the Examiner to acknowledge receipt of these documents and consider the IDS references.

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1. Objection to Claims 7, 9 and 22

Claims 7, 9 and 22 are objected to for informalities. In the Office Action, the Examiner states:

In claim 7, line 3 the word "of" is omitted. In claim 9, line 1 "on" should be "one". Claim 22, line 1, word "the" is omitted. Appropriate correction is required.

Applicants thank the Examiner for pointing out these corrections. Applicants have inserted the term "of" into claim 7, and have replaced the term "on" with the term "one" in claim 9. Claim 22 has been canceled. In view of these corrections, Applicants respectfully request the Examiner to reconsider and withdraw this objection.

2. Rejection of Claims 1, 6, 8, 10, 12-21 and 24-25
under 35 U.S.C. §112, second paragraph

Claims 1, 6, 8, 10, 12-21 and 24-25 are rejected under 35 U.S.C. §112, second paragraph as being indefinite. In the Office Action, the Examiner states:

More specifically, in claim 1, the language of "comprising one or more filaments and formed with a coating" is indefinite because it is not clear whether this language refers to coated filaments per se, or a process of making the filaments.

In claim 6, the language of "in the range of more than 30,000 Daltons" is indefinite because no range is specified. The suggested language is "molecular weight of more than 30,000 Daltons".

As to claim 8, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031,

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2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board Stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 recites the broad recitation inherent viscosity of 0.4 to 3.0 dl/g, and the claim also recites "particularly 0.7 to 1.3 dl/g" which is the narrower statement of the range/limitation.

In claim 10, language of "formed from a combination of the bioresorbable polymer with fatty acid salts" is vague and indefinite because the term "combination" is non-specific and can describe mixed, blended, grafted or polymerized.

As to claim 12, this claim is generally narrative and indefinite, failing to conform with current U.S. practice.

Claim 13 is vague and indefinite and is drawn to the future processing of the terpolymer. Also, this claim does not provide a positive recitation of the terpolymer properties.

In claim 14, line 1, the word "it" is vague and indefinite because it is not clear whether this term refers to the terpolymer or suture material. Also, the language of "formed from a combination of the bioresorbable polymer with fatty acid salts" is vague and indefinite because the term "combination" is non-specific and can describe mixed, blended, grafted or polymerized.

Claim 15 is vague and indefinite for the reasons stated above.

Claim 16 is indefinite because this claim is generally narrative and indefinite, failing to conform with current U.S. practice. Also, the language of "wherein the coating takes place by the application of a bioresorbable polymer" is vague because it does not provide a clear recitation of process steps that define how this application takes place, what is applied and the substrate that receives the applied material.

Claim 17 is indefinite because this claim is generally narrative and indefinite, failing to conform with current U.S. practice.

As to claim 18, this claim is indefinite because a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board Stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the

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remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 18 recites the broad recitation a concentration of 0.1 to 10, and the claim also recites 0.5 to 5 wt.% which is the narrower statement of the range/limitation. Also, the range 0.1 to 10 does not have units of measurements. The suggested range is 0.1 to 10 wt.%.

Claim 19-21 are indefinite because these claims are generally narrative in form, failing to conform with current U.S. practice. The language that renders these claims narrative is "wherein for coating purposes".

Claim 24 is indefinite because this claim is generally narrative in form and fails to conform with current U.S. practice. In particular, this claim does not provide a positive recitation of a process step wherein the terpolymer is melted.

Claim 25 is vague and indefinite because it is not clear whether the term "coating" in line 1 refers to the coating process or coating solution. Also, the language of "formed from a combination of the bioresorbable polymer with fatty acid salts" is vague and indefinite because the term "combination" is non-specific and can describe mixed, blended, grafted or polymerized.

Applicants respectfully traverse Examiner's rejection.

Applicants have canceled claims 12-21 and 24-25. Regarding claim 1, the phrase "comprising one or more filaments and formed with a coating" has been amended to "comprising one or more filaments, wherein the suture material is formed with a coating" to render the claim more clear. Regarding claim 6, Applicants have followed the Examiner's suggestion by deleting the phrase "in the range". Regarding claim 8, the narrower range reciting "particularly 0.7 to 1.3 dl/g" has been removed from the present claim and claimed in a new claim 26. Regarding claim 10, the term "combination" has been replaced with the term "mixture".

These amendments render the claims more clear and definite.

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Therefore, the Examiner is respectfully requested to reconsider and withdraw this rejection.

3. Rejection of Claims 12, 14 and 16-17

under 35 U.S.C. §102(b)

Claims 12, 14 and 16-17 are rejected under 35 U.S.C. §102(b) as being anticipated by Wang et al., 4,705,820 ('820). In the Office Action, the Examiner states:

Wang teaches a coating material for surgical sutures formed from a bioresorbable random terpolymer having an amorphous structure and a process for producing said suture wherein said terpolymer contains fatty acid salts and is dissolved in an organic solvent when applied to the substrate, as required by claims 12, 14 and 16-17. See abstract, column 1, lines 5-13, column 3, line 6, and lines 50-53 and Example 8.

Therefore, the teachings of Wang anticipate the invention as claimed in present claims 12, 14 and 16-17.

Applicants respectfully traverse the Examiner's rejection. The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

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Applicants have canceled claims 12, 14, 16 and 17. There is no indication of precise monomer amounts and proportions in '820. However, the terpolymer of the present invention is characterized by a defined composition of three distinct monomers glycolide, ε-caprolactone and trimethylene carbonate (TMC). Therefore, the present invention is not anticipated by '820, and Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

4. Rejection of Claims 1, 4-11, 13, 15 and 18-25

under 35 U.S.C. §103(a)

Claims 1, 4-11, 13, 15 and 18-25 are rejected under 35 U.S.C. §103(a) as being obvious over Wang et al., 4,705,820 ('820) in view of Bezwada et al., 5,371,176 ('176) and 4,994,074 ('074). In the Office Action, the Examiner states:

Wang teaches a surgical suture coating comprising an amorphous bioresorbable random copolymer, said copolymer comprising glycolide and trimethylene carbonate, that can be present in amounts within applicants' range, further teaching that his polymer can contain other monomers such as caprolactone, as required by claims 1, 4 and 5. See abstract, column 1, line 5-9 and column 3, lines 6-7. Wang does not specify the amount of said monomers that can be added. In addition, Wang teaches that his coating has an inherent viscosity of from 0.5 to 3 dl/g and a glass transition temperature of less than about 25°C, as required by claims 7 and 8. See column 2, lines 3-37. The coating of Wang can contain a plasticizer and fatty acid salts, per claims 9-10, 14-15 and 25, although silent as to the specific amount of plasticizers. See column 3, lines 45-51 and Example 8. Regarding claim 6, Wang does not teach specific molecular weight amounts of his polymer. However, he does teach that his polymer has a relatively high molecular weight in order to have a reasonable tensile strength. Note column 3, line 29-35. Accordingly, it is the examiner's position that his teaching of Wang renders obvious the requirement of claim 6 of an average molecular

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weight in the range of more than 30,000 Daltons. The skilled artisan would have been reasonably motivated to use higher molecular weight polymers in order to have relatively good tensile strength. As to claims 18-24, Wang teaches a process for coating a structure material wherein the polymer is incorporated in a concentration within applicants' range and dried. See Example 8.

Bezwada '176 teaches an absorbable polymer for use as a coating for surgical sutures comprising about 50-90 parts by weight of lactone monomers such as *e*-caprolactone and trimethylene carbonate and about 9-10 parts by weight of glycolide, wherein a mixture of lactones can be used. See abstract, and column 3, line 56 through column 4, and line 17. The polymer can also contain fatty acid salts, as set forth by applicants in claims 10, 14-15, and 25, and a plasticizer in an amount ranging from 0.5 to about 30 parts by weight, per claim 9. See column 5, lines 5-15. In addition, Bezwada '176 teaches that the coating can be applied to the surface of the suture in an amount ranging from about 0.5 to about 30 percent of the weight of the coated suture, as required by claim 11. See column 6, lines 30-42.

As set forth previously, Wang teaches that his polymer comprises glycolide and trimethylene carbonate and can comprise monomers such as caprolactone, although silent as to the specific amount of caprolactone. It would have been obvious to form a composition as taught by Wang wherein caprolactone is included, thereby using a mixture of soft monomers as taught by Bezwada '176. Furthermore, the teachings of Bezwada '176 would have provided motivation to the skilled artisan to use said mixture in the composition of Wang in amounts within the range of 10 to 50 parts by weight, (which necessarily obviate applicants' range of claim 1 and ratio of claim 4) in order to obtain a coating that is compatible with conventional solvents and aids in providing a lowered melting temperature and glass transition temperature.

As to claim 9, the teachings of Bezwada '176 of using a plasticizer in amounts within applicants' range would have provided direction to the skilled artisan at the time the invention was made to modify the composition of Wang by including 1 to 30 wt% of a plasticizer in order to enhance the performance of the polymer. Furthermore, the teachings of Bezwada '176 would have provided a suggestion and motivation to the skilled artisan to coat the composition of Wang onto suture material such that the coating represents 0.5 to about 30 wt% of the total weight of the coated suture material, as contemplated by applicants in claim 11 to result in a coated suture that is slippery and easy to manipulate without increasing the risk of the coating flaking off.

As to claims 19-23, Bezwada '176 teaches a process for producing suture material wherein a suture material is dipped in a coating solution containing organic solvents and cured in an oven at 100°-200°C (Example 8) and Bezwada '074 teaches that "once a solution of the copolymer is prepared, a suture can be coated using conventional coating techniques, e.g. dipping, spraying, etc." (column 3, lines 47-51). The teaching of Bezwada '176 would have provided direction and a suggestion to the skilled artisan at the time the invention was made to modify the process as taught by Wang, wherein after

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coating, the suture material is dried with a heating device at a temperature within applicants' range as set forth in claim 23 with the reasonable expectation of removing the solvent. In addition, the teachings of Bezwada '074 would have provided a suggestion to the skilled artisan that any conventional coating techniques known in the art such as those contemplated by applicants in claims 19-21 could be used in the process of Wang with the reasonable expectation of success of obtaining coated suture material. As to claim 22, this requirement is no more than what would be considered in the room temperature range. It would have been obvious to perform the coating process within the room temperature range in the absence of clear factual evidence to the contrary.

Therefore, the combined teachings of Wang and Bezwada '176 and '074 would have rendered obvious the invention as claimed in present claims 1, 4-11, 13, 15, and 18-25.

Applicants respectfully traverse the rejection. To establish a *prima facie* case, the PTO must satisfy three requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art reference must teach or suggest all the limitations of the claims. *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

Applicants have canceled claims 13, 15 and 18-25. Applicants respectfully traverse the Examiner's rejection. The present suture

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materials are not rendered obvious by the patent references.

The present terpolymer is characterized by both a high molecular mass of more than 30,000 Daltons and a waxy consistency. This has a beneficial effect on suture handling and performance, namely its knotting characteristics. See specification at paragraphs [009], [018], [035], [037] and [039]. That is to say, sutures prepared according to the present invention have good knot running down behavior and good knot security.

The completely amorphous polymer structure allows less bending stiffness (which is undesirable with sutures) and improved degradation and bioresorption behavior.

The waxy terpolymer promotes formation of a stable surface film on the entire suture surface; there is no stripping or peeling of the coating when the suture passes body tissue.

Low glass transition temperatures of the terpolymer down to -40°C, preferably not more than 0°C (see paragraph [011]) that are controlled by terpolymer composition ensure beneficial characteristics for suture applications, without need for plastifier or lubricant additives.

The low glycolide amount in the terpolymer allows good solubility in common non-toxic organic solvents.

One of ordinary skill in the art would not arrive at the present suture materials from the cited references. Specifically, the disclosure of '820 refers to copolymers (all polymers presented

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in the examples are composed of only two monomers) and does not exhibit defined terpolymer compositions. The polymer of '820 is not indicated to be waxy. Instead, it has good tensile strength which is not a relevant feature of the present waxy terpolymers.

Further, patent '176 includes castor oil as a polymer component to act as a lubricant. Such a polymer differs from the terpolymer according to the present invention in composition, structure (partially crystalline as obvious from melting temperature) and material characteristics. The '176 polymer has superior knot run performance, but has reduced knot security, as evident from Table 2 (col. 9). The suture according to the present invention has superior knotting characteristics, and in particular, knot security, without a need for plastifier or lubricant additives.

Regarding '074, this document discloses partially crystalline low molecular weight copolymers based on caprolactone and glycolide. Glycolic acid is added to control molar mass and viscosity. Such a polymer differs from the inventive terpolymer in composition, structure and characteristics.

Additionally, with regards to viscosity data, such data from the references cannot be readily compared to that contemplated by the present invention without recalculating and fitting to adequate conditions, because viscosity data are significantly affected by the analytical conditions employed, namely concentration.

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In view of the foregoing, the present invention is not obvious over the patent references, and One of ordinary skill in the art cannot arrive at the present invention from the cited references. Therefore, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

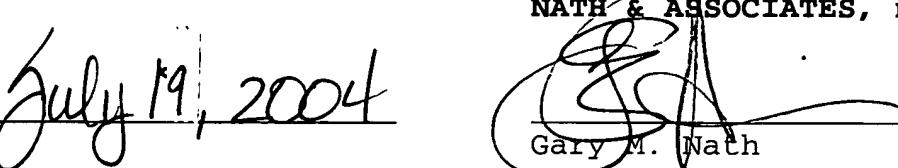
CONCLUSION

Based upon the above amendments and remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the references of record. The Examiner is therefore respectfully requested to reconsider and withdraw the outstanding objection and rejections and allow all pending claims presented herein for reconsideration. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,

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